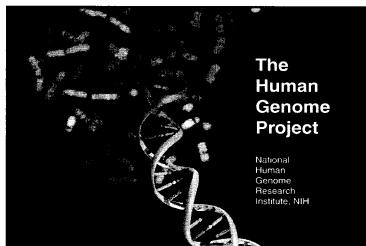
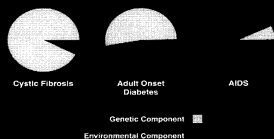


Virtually All Diseases (Except Maybe Trauma)
Have a Genetic Component



COOL THINGS ABOUT THE GENOME

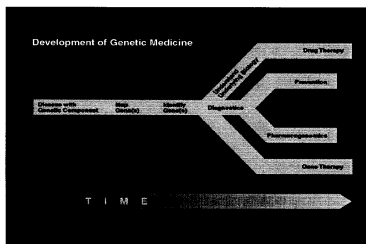
Humans have fewer genes than expected

Human genes make more proteins than those of other critters

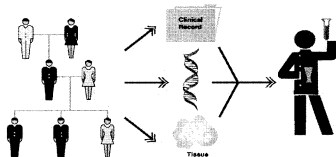
Humans have adopted 200 genes from bacteria

Male mutation rate is twice that of females

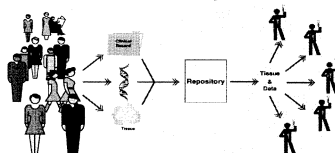
"Junk" DNA Contains the Remnants and Raw Materials for Evolution



The Old Way



The New Way





Research Participant

Shifting Emphasis in Research

Research Protocol Clear at the Outset
(Narrow Specific Consent)



Research Uses Broad or Unanticipated
("Blanket" Consent or Recontact to Reconsent)

Shifting Emphasis in Research

Physical Risks



Psychosocial Risks

Shifting Emphasis in Research

Publicly Funded Research & Research Resources



Privately Funded Research & Research Resources

ISSUES TO CONSIDER

Family Members and Informed Consent

Community Consultation

Stored tissue research

Blanket Consent

Disclosure of Research Results

ISSUES TO CONSIDER

Family Members and Informed Consent

Community Consultation

Stored tissue research

Blanket Consent

Disclosure of Research Results

Family Members and Informed Consent

"Human Subject" means a living individual about whom an investigator conducting research obtains

(1) data through intervention or interaction with the individual,

or

(2) identifiable private information.

Waiver

1) research is no more than minimal risk

2) waiver does not adversely affect rights and welfare

3) research not practicable without waiver

4) whenever appropriate, subjects provided with information after participation

Family Members and Informed Consent

Considerations

Any evidence of harms in the past?

Involving family members directly in research may in some instances create harms for proband.

Genotype of unconsented individuals may occasionally be revealed by research studies.

How far in the pedigree do you go?

ISSUES TO CONSIDER

Family Members and Informed Consent

Community Consultation

Stored tissue research

Blanket Consent

Disclosure of Research Results

Community Consultation

Research involving identifiable populations

-Risk of stigma may extend beyond individual

-Should the community be involved in research design and implementation?

ISSUES TO CONSIDER

Family Members and Informed Consent

Community Consultation

Stored tissue research

Blanket Consent

Disclosure of Research Results

Many groups have made recommendations.

Researchers and IRBs still confused

ISSUES TO CONSIDER

Family Members and Informed Consent

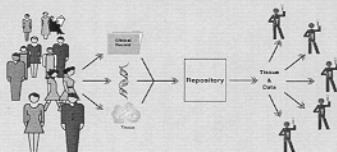
Community Consultation

Stored tissue research

Blanket Consent

Disclosure of Research Results

The New Way



Alternatives for Consent

For Large Genetic Epidemiological Studies

Anonymization of specimens

Narrow individual consent with recontact for future uses.

Blanket consent for all uses

ISSUES TO CONSIDER

Family Members and Informed Consent

Community Consultation

Stored tissue research

Blanket Consent

Disclosure of Research Results

"The disclosure of research results to subjects represents an exceptional circumstance"

NBAC, 1999

Medical Records Privacy Regulations

(currently undergoing review)

An individual has a right of access to inspect protected health information about the individual except:

- **when access would violate CLIA**
- **research that includes treatment is in progress**

Disclosure if:

- 1) **Finding is scientifically valid and confirmed**
- 2) **Results obtained in CLIA approved lab**
- 3) **Finding has significant implications for subject's health**
- 4) **Course of action to ameliorate or treat readily available**
- 5) **Ability to provide care and counseling**

**IRB Guidebook is dusty
and out of date for genetics
research**